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September 17, 1999

BY HAND DELIVERY

Ms. Magalie Salas, Secretary
Federal Communications Commission
The Portals TW-A325
445 12th Street, SW
Washington, DC 20554

Re: In the Matter of
Amendment of Parts 2 and 95 of the Commission's Rules
to Create a Wireless Medical Telemetry Service
ET Docket No. 99-255
Our File 05013/001001

Dear Ms. Salas:

Enclosed please find a **confirmation copy** and four additional copies of the above-referenced comments of PCTEST Engineering Laboratory, Inc., which were timely submitted electronically on September 16, 1999.

Please contact the undersigned if you have any questions regarding this matter.

Very truly yours,

Terry G. Mahn

/seg

Enclosures
[Original/copies]
cc: R. Ortenz, PCTEST, Inc.

101945.W11

Before the
Federal Communications Commission
Washington, D.C. 20554

In the Matter of

Amendment of Parts 2 and 95 of the	)	
Commission's Rules to Create a Wireless	)	**ET Docket No. 99-255**
Medical Telemetry Service	)	

To : The Commission

COMMENTS OF PCTEST ENGINEERING LABORATORY, INC.

1. PCTEST Engineering Laboratory, Inc. ("PCTEST Lab"), hereby submits these comments in response to the Commission's Notice of Proposed Rulemaking ("NPRM") to create a Wireless Medical Telemetry Service ("WMTS"), released on July 16, 1999. PCTEST Lab favors the adoption of a new spectrum allocation and emissions standards for WMTS but believes that the proposed rules do not go far enough toward protecting patients from potentially harmful exposure to RF radiation. Specific absorption rate (SAR) testing by PCTEST Lab using a representative transmitter operating in the proposed WMTS allocations above 1 GHz reveals that medical telemetry devices may be capable of exceeding the applicable RF radiation standards required for portable RF devices under Section 2.1093 of the Commission's Rules. Accordingly, PCTEST Lab recommends that the rule proposals be amended to require WMTS devices to be evaluated for RF exposure prior to equipment authorization and use. Moreover, because WMTS represents a new class of transmitters on the market whose measurement procedures are currently non-existent, PCTEST Lab recommends that they be subject to certification,

rather than Declaration of Conformity (DOC), until the Commission has developed greater market experience with their use.

BACKGROUND AND INTEREST

2. PCTEST Lab is an EMI/EMC laboratory engaged in the testing of devices for compliance with U.S., Canada, Japan, Australia/New Zealand, Taiwan, and European regulations. PCTEST Lab is an accredited independent testing laboratory recognized under NIST's National Voluntary Laboratory Accreditation Program ("NVLAP"), meeting the requirements of ISO/IEC Guide 25 and ISO 9002 (ANSI/ASQC Q92-1987) as a supplier of calibration or test results. PCTEST Lab's NVLAP accreditation covers the areas of Electromagnetic Compatibility (EMC), Telecommunications, and FCC compliance. In addition, PCTEST Lab performs DOC testing procedures for a variety of products under the Commission's rules.

3. PCTEST Lab has performed numerous testing and data submissions under Commission rules for a broad spectrum of RF devices. PCTEST was one of the first laboratories to provide routine environmental evaluations of portable and mobile devices under the RF exposure limits adopted by the Commission in 1996, which mandate compliance with ANSI/IEEE C95.1-1992 "IEEE Standards for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz"[1]. As a result of its commitment to RF radiation safety testing and evaluation, PCTEST has become one of the few laboratories worldwide that is capable of performing SAR and Maximum Permissible Exposure ("MPE") testing of RF transmitters under the Commission's RF exposure limits. PCTEST Lab's comments in this NPRM, therefore, are rooted in its experience and recognized expertise in this field.

[1] See 47 CFR §§ 2.1091, 2.1093

I. RF EXPOSURE EVALUATION SHOULD BE REQUIRED

4. PCTEST Lab fully supports the establishment of the WMTS and the proposals to adopt minimal technical standards to allow for product innovation[2]. PCTEST Lab believes the public will be served by creating this new primary service, however, it has several concerns regarding the NPRM's failure to address RF radiation exposure for WMTS devices.

5. In this regard, PCTEST Lab strongly believes that RF exposure evaluations should be required for any portable transmitters held, or capable of being used in close proximity to, the human body. Because WMTS devices will normally be used on or very near to the human body, they have the potential to expose patients to the biological hazards associated with RF radiation. The Commission normally requires a routine environmental evaluation performed on portable devices designed to be used so that the radiating structure(s) of the device is/are within 20 cm of the body of the user[3]. Even though WMTS devices have a relatively low power output, their use in close proximity to the patient (i.e. affixed to the body or clothing), continuously and over comparatively long periods of time raise exposure concerns[4]. In many instances, the radiating element of the transmitter will be permitted to come in direct contact with the skin, separated only by the thickness of the patient's clothing or covering. Therefore, pursuant to Commission's current practice, routine environmental exposure measurements should be performed.

6. Further, the analysis below shows a clear potential for these devices to produce SAR levels that exceed current RF exposure guidelines. The proposed rules for the WMTS would permit operation in the frequency bands 608-614 MHz, 1385-1390 MHz, and 1429-1432 MHz or, alternatively, 608-614 MHz and 1391-1400 MHz. At

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[2] See NPRM at ¶ 34.

[3] See 47 CFR § 2.1093

[4] Unlike medical implant transmitters, which must use their battery power very sparingly for telemetry in order to save power for therapeutic use over the multi-year life of the implant, external medical telemetry transmitters would not have such an inherent self-limiting restraint on use of battery power. Indeed, one

frequencies above 1 GHz, the proposal permits a field strength level of 740 mV/m measured at 3 meters using an instrument with a 1 MHz resolution bandwidth and an average detector. The proposed NPRM also permit variable transmission bandwidths that would allow one transmitter to occupy the entire frequency band of operation.

7. The theoretical power required to generate a field of 740 mV/m at 3 meters can be calculated using standard engineering formulas. Two scenarios are possible related to phase addition, or lack thereof, of the reflected component typically associated with Open Area Test Site (OATS) measurements. Assuming a 6 dB factor for the reflected component, a power level of 25 mW into a tuned dipole antenna would be required to produce a field strength of 740 mV/m at 3 meters. Assuming a 0 dB factor for the reflected component (i.e., no reflected component), a power level of 100 mW into a tuned dipole antenna would be required to produce a field strength of 740 mV/m at 3 meters. A tuned dipole antenna was used in the above calculations based on the NPRM's proposal to report effective radiated power (ERP) for purposes of frequency coordination[5].

8. It should be noted that under the provisions of the NPRM, specific measurement instrument resolution bandwidths are required to be used in making measurements to show compliance with the field strength limits[6]. This requirement coupled with the ability of transmitters to occupy the entire frequency band would permit wireless medical telemetry transmitters to have output powers up to 900 mW. For example, a transmitter occupying the entire 1391-1400 MHz band could theoretically produce a total power of approximately 225 mW to 900 mW depending on measurement site uncertainties related to the level of the reflected component.

9. Based on PCTEST Lab's experience with SAR measurements on various devices used in close proximity to the body, the proposed power levels for WMTS transmitters

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of the benefits of an external transmitter is that it provides a wireless link capable of operating over several hours while a patient is hospitalized or while in medical care.

[5] See NPRM at ¶ 31.

[6] See NPRM at ¶ 36.

could exceed the Commission's RF exposure limits. Accordingly, a preliminary test was conducted using a dipole antenna to determine the power level at which a medical transmitter would produce a SAR level of 1.6 W/kg. This preliminary test was modeled to simulate the typical usage condition of WMTS transmitters as they are currently configured and operated in a hospital environment with the antenna placed close to the body. PCTEST Lab's test results indicate that at **1400 MHz**, with a power output level of **24 mW**, electromagnetic radiation from a dipole antenna held in close proximity to the human body has the potential to produce SAR levels of **1.7 W/kg or 1.7 mW/gm** averaged over 1 gram. This is above the level specified in the Commission's Rules for general population/uncontrolled environment scenarios.

10. Moreover, as previously stated, the measurement requirement for using a 1 MHz resolution bandwidth would permit a higher total power for wideband signals under the proposed rules. A 5 MHz bandwidth system (1385-1390 MHz), for example, could radiate at 125 mW total power and still be in compliance under the proposed rules. For a 9 MHz bandwidth system (1391-1400 MHz), the maximum power would approach 225 mW. These calculations are based on phase addition of a 6 dB reflected component when measured at an OATS facility. Power levels could be up to 6 dB higher if the measurement setup and equipment did not accurately account for any reflected component. Clearly, at these power levels, there is the potential for RF exposure to be exceeded by WMTS transmitters. In view of this, PCTEST Lab considers it essential that these devices be required to have information filed routinely to show compliance with the appropriate RF exposure limits.

11. The Commission's RF radiation exposure rules were adopted to meet its responsibilities under the National Environmental Policy Act of 1969.[7] Because there are currently no federally-mandated RF exposure standards, the Commission rules are based on recommendation of ANSI /IEEE and the National Council on Radiation Protection and Measurements (NCRP) for human exposure to RF electromagnetic fields. For devices operating in close proximity to the body (i.e., portable devices) the rules prescribe an SAR limit that is based on "threshold levels" for protected biological hazards depending on whether the device is used in an employment (so-called occupational/controlled exposure) or by the general public (so-called general population/uncontrolled exposure). For a device used or worn by the general public, the SAR limits are .08 W/kg as averaged over the whole-body and a spatial peak SAR not exceeding 1.6 W/kg as averaged over any 1 gram of tissue.[8]

12. Devices not specifically covered by the rules are "categorically excluded" from any routine evaluation for RF exposure. Of relevance to this proceeding, RF devices authorized under the Part 95 Personal Radio Services are categorically excluded from RF exposure testing or compliance. Moreover, no devices authorized under the DOC procedures have even been made subject to SAR evaluation. Should the Commission adopt the proposed rules, therefore, medical telemetry devices operating above 1 GHz would not have to be tested for SAR compliance even though they potentially expose patients to RF radiation hazards as demonstrated by PCTEST Lab. Accordingly, PCTEST Lab urges that the following rule change be adopted:

> § **2.1093(c)** In the first sentence after "unlicensed NII devices" add ",medical telemetry devices authorized under the Part 95 subpart H Wireless Medical Telemetry Service"

[7] See 47 CFR Section 2.1093.
[8] 47 CFR Section 2.1093(d)(2). Exceptions are the hands, wrists, feet and ankles where higher limits apply.

WMTS device manufacturers will be able to show compliance with the Commission's SAR limits by reducing the power, bandwidth, developing safety shielding for their devices, and/or increasing the separation distance between the patient's body and WMTS device radiating element.

II. THE COMMISSION SHOULD REQUIRE CERTIFICATION INSTEAD OF DOC PROCEDURE FOR WMTS.

13. In the NPRM[9], the Commission proposed to authorized WMTS under the DOC procedures. PCTEST Lab has several concerns with placing WMTS devices under this authorization program.

14. First, no specific measurement procedures exist for WMTS devices. For frequencies above 1 GHz, there is little or no guidance for EUT setup, measurement equipment, or OATS test site acceptability. Considering the variations that can be obtained from just the reflected component, the likely use of wire type antennas placed close to the body and the attachment of multiple additional leads to these types of transmitters, PCTEST Lab questions the wisdom of putting these devices under the DOC program. Second, without documented procedures and test site requirements there is considerable potential for a wide variability in test results data from one site to another. Finally, lacking any documented test procedures, placing WMTS equipment under the DOC program would appear to be in conflict with the Commission's policy for including devices in the Telecommunication Certification Body (TCB) program[10]. In view of these deficiencies, PCTEST Lab recommends placing WMTS devices, at least initially, under the certification program.

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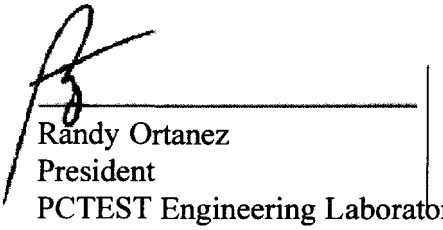
[9] See NPRM at ¶ 39.

[10] See Public Notice, DA 99-1640, FCC Provides Further Information on the Accreditation Requirements for Telecommunications Certification Bodies, GEN Docket 98-68, p.2, note (2) released August 17, 1999. Here, the Commission is categorically excluding from the TCB program certain devices until appropriate measurement procedures have been published.

CONCLUSION

15. PCTEST Lab has carefully evaluated a representative telemetry transmitter operating above 1 GHz at the field strength levels proposed in the NPRM and has found the device to be capable of exceeding the RF radiation exposure limits required for similar RF devices to which the public may be exposed. PCTEST Lab submits that the general patient population using these new telemetry devices must be protected against exposure and, therefore, urges the Commission to adopt the recommendations set forth herein. Given the importance of ensuring patient safety from WMTS devices, the compliance obligations imposed on device manufacturers will clearly serve the public interest.

Respectfully submitted,



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